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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,620

06/19/2006

Annie Bardat

0040-0168PUS1

1914

2292 7590 12/29/2008  
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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

12/29/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,620	<b>Applicant(s)</b> BARDAT ET AL.	
	<b>Examiner</b> HOPE A. ROBINSON	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/14/06; 1/6/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's election with traverse of Group I (claims 1-19) is acknowledged.
2. The traversal is on the grounds that the claims should not be restricted as there is unity of invention with the special technical feature presented in the claims. This argument is not persuasive as the claimed invention does not escape the prior art, thus does not possess a special technical feature or unity of invention. Thus the lack of unity of record is proper and is final.
3. Claims 1-21 are pending. Claims 1-19 are under examination. Claims 20-21 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

### ***Information Disclosure Statement***

4. The Information Disclosure Statements filed on January 6, 2006 and November 14, 2006 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office

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action. Note however, that some of the references have been lined through because they represent an improper citation (missing date or author etc.).

### ***Claim Objection***

5. Claims 2 and 18-19 are objected to because of the following informalities:

Claim 2 is objected to because the claim doesn't appear to further limit independent claim 1.

For clarity and precision of claim language, claim 18 should be amended to read, "intended for therapeutic use".

Claim 19 is objected to because it depends from claim 13 and claim 17 which both depend from claim 1. It is suggested that the claim is amended to depend from claim 17 and not claim 13.

Correction of the above is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

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Claim 1 and the dependent claims hereto are indefinite because the claimed method is confusing with the recitation of "including or includes" because it is unclear what other method steps are included and the claim language does not set forth the specific steps used in order. For example, "A process for obtaining cryoprecipitable proteins comprising:

- (a) contacting a protein of interest with a stabilizing and solubilizing formulation comprising a mixture of arginine
- (b) transform said protein into a freeze-dry form
- (c) perform a virus inactivation step"
- (d) recovery the protein".

As the method is not outlined as exemplified with an organized series of steps, the claim is confusing.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 14-18 rejected under 35 U.S.C. 102(b) as being anticipated by Branovic et al., (Applied Biochemistry and Biotechnology, vol. 69, 1998, pages 99-111.

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The claimed invention is directed to a method to obtain cryoprecipitable proteins using a virus inactivation step, a freeze dried form and stabilizing/solubilizing formulation (see claim 1 for example) and further comprising FVIII, VWF, FXIII, fibrinogen and fibronectin as the proteins ( see claim 16, for example).

Branovic et al., disclose a FVIII wherein a double virus inactivation step is utilized to isolated from cryoprecipitate. The Branovic et al., reference discloses that “viral inactivation was performed by combination of S/D treatment and heating of final freeze-dried product...” (see page 99 of the reference). Branovic et al., discloses the use of stabilizers (page 103 Figure 1 flow chart ) and uses an anhydrous form of trisodium citrate (Figure 1 flow chart pages 102-104). The method of Branovic et al., uses filtration and solvent detergent (see Figure 1).The reference discloses purification of a concentrate (see pages 100-101). Therefore, the limitations of the claims are met by the reference.

### ***Conclusion***

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652